Small scale pharma Industries

2048. SHRI A. VIJAYARAGHAVAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Schedule M had been implemented on Small Scale Pharma Industries (SSPI);

(b) if so, the details including the number of SSI units that implemented Schedule M, number of SSI units yet to be implemented, number of SSI units whose licenses of drug manufacture had been cancelled/suspended due to not implementation of Schedule M, and number of SSI units closed after enforcing schedule M, category-wise and State-wise on today; and

(c) if so, whether steps would be taken to examine problems due to implementation of Schedule M and to keep in abeyance above implementation till issues are resolved?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) Yes Sir, Schedule M to the Drugs & Cosmetics Rules prescribes the requirements of Good Manufacturing Practices which are to be followed by all drug manufacturing units including Small Scale Industries in the country. These provisions are enforced by the State Drug Control Authorities.

(b) The details regarding number of SSI units who have implemented Schedule M, number of SSI units yet to be implemented, number of SSI whose licenses of drug manufacture had been cancelled/suspended due to non-implementation of Schedule M and number of SSI units closed after enforcing Schedule M till date had been called from different States as the Schedule M is enforced by respective State Drug Controller. Data available in this Directorate for the year 2005 is given in the enclosed Statement (*See* below).

(c) Good Manufacturing Practice (GMP) is an ongoing process of manufacturing of drugs and same is revised from time to time.

Schedule was revised by the Government of India, Ministry of Health *vide* Gazette Notification GSR 854 (E) dated 11.12.2001 and an extension up to three and half years was given for its implementation for the existing units and has been finally implemented since 1st July, 2005 *vide* GSR No. 738 (E) dated 8th November, 2004. Therefore, enforcement of Schedule M cannot be kept in abeyance, any further.

Statement

Feed back received from following States regarding implementation of revised Schedule M in respect of Small Scale Industry Pharma Units

Sl. No.	State	Date	No. of SSI units that implemented Schedule M	No. of SSI units where Schedule M being implemented	No. of SSI units cancelled/Non-functional or not made changes
1	Haryana	27/1/06	111	70	39 not complying 21 suspended 23 cancelled
2	Maharashtra FDA	28/2/06	31	38	11 cannot make change
	Nashik		—	—	2 cancelled
	Amaravati	4.2.06	Nil	Nil	Stop production order 6 Voluntary stop production 1 1 cancelled
3	Tripura	22/2/07	—	—	Note able to fulfil-3
4	Rajasthan	3/2/06	—	—	Nil
5	U.P.	3/2/06	126	Not clarified	Nil
6	M.P.	1/2/06			32 cancelled 40 suspended 40 stop manufacturing
7	Jharkhand	3/1/06	—	11	8 surrendered 2 cancelled
8	Uttaranchal	3/2/06	2	2	1
9	Sikkim	2/8/06	1	5	—
10	Goa	6/3/06	35 WHO GMP	13	6 closed 18 not complying
11	Gujarat		407	—	Not complied 176 Exempted 198 64 cancelled
12	Andaman & Nicobar	15/2/06	Nil	—	
13	H.P.	1/2/06	83	—	1 closed 1 notice issued
14	Karnataka	30/1/06	—	—	22 non-complaint 45 notices issued 18 stop production 2 surrendered
15	Kerala	28/1/06	11	16	24